

Remarks

Status of the Claims

By the foregoing amendments, claims 1, 15-17, 19, and 39-44 are sought to be amended. New claims 45-61 are sought to be added. Support for the amendments to the claims and for new claims 45-61 can be found throughout the specification, for example, throughout pages 8-12, and the Examples. Therefore, these amendments do not introduce new matter, and their entry and consideration are respectfully requested. Upon entry of the foregoing amendments, claims 1-20, 22, 23, 25-29 and 32-61 are pending in the application, with claims 1, 17, 19, 39-44 and 46 being the independent claims.

Traversal of Restriction Requirement

The Examiner has restricted the currently pending claims to six (6) groups, alleging that the claims in these groups each represent distinct and independent inventions. Applicants respectfully disagree with the Examiner and hereby make the election of Group I noted above, with traverse.

Groups I and II as set forth by the Examiner contain fifteen claims that are common to both groups. The Examiner has noted that the claims of Group I are directed to vectors for delivery of a virus to a target cell within a host animal comprising a cell-targeting ligand, which is a protein peptide or hormone, and methods for preparing said vectors. The Examiner has also set forth that the claims of Group II are directed to vectors for delivery of a virus to a target cell within a host

animal comprising a cell-targeting ligand, which is an antibody or antibody fragment, and methods for preparing said vectors. The Examiner asserts that:

Groups I and II are patentably distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions: proteins, peptides, and hormones vs. antibodies and antibody fragments.

Office Action at page 4, last paragraph. The Examiner also alleges that Groups III and IV, and V and VI, respectively, are patentably distinct from each other for the same reason. Applicants respectfully disagree with the Examiner's assertions.

Applicants submit that by definition, an antibody is a protein. For example, in Alberts *et al.*, the glossary entry for "antibody (immunoglobulin)," states: "Protein produced by B lymphocytes in response to a foreign molecule or invading organism." Alberts et al., *Molecular Biology of the Cell*, Third Edition, Garland Publishing, Inc., New York, Glossary at page G-2, entry for "antibody (immunoglobulin)" (1994) (copy attached herewith as Appendix I). Therefore, Group I, directed to "proteins" must necessarily encompass Group II, directed to "antibodies and antibody fragments" (molecules that are clearly proteins). Hence, Applicants submit that Groups I and II, which differ only in the type of cell-targeting ligand used, cannot be patentably distinct inventions.

As set forth in M.P.E.P. § 803.06:

Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition.

M.P.E.P. § 803.06, 800-42. Applicants respectfully submit that the claims set forth in Groups I and II are not directed to distinct inventions, rather they are different definitions of the same disclosed subject matter, varying in breadth, i.e., a protein is broader than, and hence encompasses, antibodies and antibody fragments. The fact that an exemplary embodiment of the present invention (e.g., wherein the cell-targeting ligand is an MAb) would be encompassed by the claims of both Group I and II, necessarily means that Group I and Group II *cannot* be directed to patentably distinct subject matter, and hence, as set forth in M.P.E.P. § 803.06, restriction therebetween should not be required.

Applicants respectfully submit that, even assuming *arguendo* that proteins and antibodies represent patentably distinct *species*, there can be no restriction between claims that overlap in scope. At best, an election of species requirement between some distinct species may be warranted in the present case, but clearly not a restriction between the claims in Groups I and II. Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement, and that all claims of the presently claimed invention be searched together. At the very least, Applicants request that the claims in Groups I and II be combined into a single Group. Alternatively, requirement for an election of species may be required by the Examiner, but it is not clear to Applicants what patentably distinct species may exist in the present claims.

Similarly, the Examiner has required restriction between claims 19, 20, 22, 23, 25-29, 37 and 38 in Groups III and IV. Applicants note that these two groups have nine overlapping claims, and also have between one and three claims that overlap

with the claims in Groups V and VI. The Examiner contends that the patentably distinct feature between the claims of Groups III and IV is that Group III claims encompass cell-targeting ligands which are proteins, peptides or hormones, while Group IV claims encompass cell-targeting ligands which are antibodies or antibody fragments. As noted above, proteins must necessarily encompass antibodies and antibody fragments, and hence, the claims of Group III encompass the claims of Group IV. Therefore, restriction between these two groups cannot be required under M.P.E.P. § 803.06. Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement, and that all claims of the presently claimed invention be searched together. At the very least, Applicants request that the claims in Groups III and IV be combined into a single Group. Alternatively, requirement for an election of species may be required by the Examiner, but it is not clear to Applicants what patentably distinct species may exist in the present claims.

Applicants also note that Groups V and VI, requiring restriction between claims 25, 29, 29 and 39-44, have seven overlapping claims (as well as claims overlapping with Groups III and IV). The Examiner has noted the reason that the claims in these Groups are patentably distinct is that the cell-targeting ligand in Group V is a protein, peptide or hormone, while in the claims in Group VI, the cell-targeting ligand is an antibody or an antibody fragment. As discussed above, the claims in Group V utilizing a protein cell-targeting ligand must necessarily encompass the claims in Group VI, utilizing an antibody or antibody fragment cell-targeting ligand. Therefore, restriction between these claims is not proper under M.P.E.P. § 803.06. Applicants respectfully request that the Examiner reconsider and withdraw the

restriction requirement, and that all claims of the presently claimed invention be searched together. At the very least, Applicants request that the claims in Groups V and VI be combined into a single Group. Alternatively, requirement for an election of species may be required by the Examiner, but it is not clear to Applicants what patentably distinct species may exist in the present claims.

Applicants also note that the Examiner has not set forth why examination of the claims of the entire application, much less between the allegedly distinct Groups of claims, would require serious burden. As required under M.P.E.P. § 803:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct invention.

M.P.E.P. § 803, 800-4. Applicants therefore submit that the restriction requirement is incomplete. Furthermore, Applicants submit that the search and examination of the claims of the present application, would not place an undue burden on the examiner within the meaning set forth by M.P.E.P. § 803.

Finally, in attempting to understand to the Restriction Requirement set forth by the Examiner, numerous conversations were held between Applicants' undersigned representative, the Examiner, and the Examiner's supervisor, Examiner Shukla. During a final discussion with Ms. Yvonne Eyler, a Training Quality Assurance Specialist for Art Unit 1632, Ms. Eyler indicated to Applicants' undersigned representative that the Restriction Requirement set forth on May 10, 2006, was not proper, for the reasons outlined herein above. Ms. Eyler recommended that an interview be conducted between Applicants' representatives, Exrs. Chen and. Shukla and Ms. Eyler, to determine a more proper format for the Restriction Requirement.

Applicants have filed herewith a request for Examiner interview specifically requesting that such an interview be scheduled prior to the issuance of the next communication from the Office.

In summary, Applicants respectfully request that the Restriction Requirement of May 10, 2006, be reconsidered and withdrawn by the Examiner, and that all claims of the presently claimed invention be examined together. At the very least, Applicants request that the claims in Groups I and II; the claims in Groups III and IV; and the claims in Groups V and VI, be recombined into three Groups, respectively.

CHANG *et al.*

- 21 -

Appl. No.: 10/820,144
2474.0070003/BJD/JKM

It is not believed that extensions of time are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Jeffrey K. Mills
Agent for Applicants
Registration No. 56,413

Date: November 13, 2006

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

605146_1.DOC